

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER for: 020702, S018**

**STATISTICAL REVIEW(S)**

Memorandum

Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research

Date: OCT 28 1999  
From: David Hoberman, Ph.D., HFD-715  
Subject: Lipitor labelling  
To: File (NDA# 20-702/SE1-018)

There was no statistical review required for this labelling change. The 25th, 50th and 75th percentiles of percent change from baseline of HDL-C was requested from the sponsor. This request was similar to the one made of Merck for its drug Zocor.

*[Signature]*

David Hoberman, Ph.D.

Concur: Dr. Sahlroot *for* *[Signature]*  
10-28-99

Dr. Nevius *[Signature]* 10-28-99

cc:  
Arch NDA# 20-702  
HFD-510  
HFD-510/DOrloff, MSimoneau  
HFD-715/DHoberman, TSahlroot, DOB2, Chron

APPEARS THIS WAY  
ON ORIGINAL